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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-02-02

October 2, 2001

Henry Torres, President
Empire Seafood, Incorporated
7850 N.W. South River Drive
Medley, Florida 33166

Dear Mr. Torres:

We inspected your seafood processing plant, located at the above address, on March 19-20, 2001 and found that you have serious deviations from the seafood processing (HACCP) regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your cooked frozen lobsters, raw frozen lobster tails and scombrototoxin (histamine) forming fish species to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have HACCP plans for cooked frozen lobsters to control the food safety hazard of pathogen survival through cooking and proper cooling of the cooked lobsters or for raw frozen lobster tails to control the food safety hazard of sulfites. (this deviation was previously brought to your attention in our letter of June 18, 1998)

You must have a HACCP plan that lists all appropriate critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrototoxin (histamine) forming fish species does not list a critical limit at the receiving critical control point for adequate ice or other cooling media to control the food safety hazard of histamines. You must also implement adequate monitoring and record keeping procedures for this critical limit.

You must adequately monitor sanitation deficiencies and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the safety of water used in the manufacture of ice or the maintenance of hand washing, hand sanitizing, and toilet facilities with sufficient frequency to ensure control as evidenced by the presence of discolored ice in your ice storage bin and no hot water available in the restrooms.

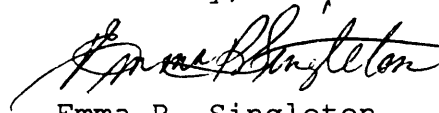
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans, sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the seafood processing (HACCP) regulations and the Good Manufacturing Practice (GMP) regulations for foods (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in dark ink, appearing to read "Emma R. Singleton", written in a cursive style.

Emma R. Singleton
Director, Florida District